

**BIOALTUS PHARMACEUTICALS PVT.LTD.**

19-20 Industrial Area, Baddi -173205 Distt. Solan

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

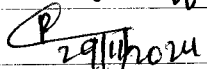
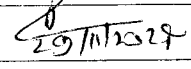
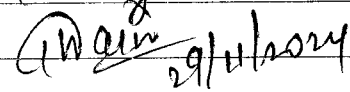
Product Name	Sacubitril 24 mg & Valsartan 26 mg Tablets (Sacubrook-V 50)	A.R. No.	BRDII/11/24/BD/1457TF
Master/FG B. No.	BD242255/ BD242255A	Master/FG B. Size	8.20 Lac/2.0Lac
Mfd. By	Self	Sample Qty.	90 Tablets
MFD.	NOV.2024	Date of Receipt	29/11/2024
EXP.	OCT.2026	Date of Release	29/11/2024

RESULTS OF ANALYSIS**Reference to Protocol : In House Specification**

S.No.	Test	Result	Specification
1.	Description	Light Pink color, elongated, biconvex film coated tablet, plain on both sides.	Light Pink color, elongated, biconvex film coated tablet, plain on both sides.
2.	Identification (By HPLC) For Sacubitril For Valsartan	Complies Complies	To Comply To Comply
3.	Average weight	0.20539 gm	0.2050 gm $\pm$ 3%
4.	Disintegration	Min. 09 minute, 13 seconds Max. 09 minute, 56 seconds	NMT 30 minutes
5.	Uniformity of weight	Min.0.2010 gm, Max.0.2092 gm	$\pm$ 7.5% of average weight
6.	Dissolution (By HPLC) For Sacubitril For Valsartan	Min. 86.05%, Max. 100.05% Mean 93.56 % Min. 83.20 %, Max. 96.54 % Mean 90.12 %	Q.NLT 75% Q.NLT 75%
7.	#Related Substances (By HPLC) Di- Acid Impurity Methyl Impurity Cyclic Impurity Maleic Impurity Any Individual unknown Impurity Total Impurities	Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected	NMT 1.0 % NMT 1.0 % NMT 1.0 % NMT 1.0 % NMT 0.5 % NMT 2.5 %
8.	Assay (By HPLC) Each Film coated tablet contains: Sacubitril 24 mg Valsartan IP 26 mg	24.79 mg (103.3 %) 25.64 mg (98.6%)	NLT 21.6 mg & NMT 26.4mg (NLT 90.0% & NMT 110.0%) NLT 23.4 mg & NMT 28.6 mg (NLT 90.0% & NMT 110.0 %)

Remark: In the opinion of the undersigned, the sample referred to above is of ~~standard quality~~ **is not of standard quality** as defined in the Act and the Rules made there under for the reasons given below: Complies as per **In House Specification No. (BRDII/QC/FPS/344F1)**

#Tests refer to Vorick Lab Report No. VAF241123259

	Prepared By	Checked By	Approved By
Name	Pateek kaur	Priyanka	Harpreet kaur
Designation	QC officer	Reviewer	Manager QC
Sign / Date	 29/11/2024	 29/11/2024	 29/11/2024

B. Pharma
Ref no. 48650